UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA v. CHRISTOPHER KYLE JOHNSTON, TRENT BROCKMEIER, and CHRISTOPHER CASSERI	Crim. No. 20-800 (ESK) *Document Electronically Filed*

DEFENDANT CHRISTOPHER KYLE JOHNSTON'S BRIEF IN OPPOSITION TO THE GOVERNMENT'S MOTION IN LIMINE TO PRECLUDE EXPERT TESTIMONY

GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07030
(973)596-4500
Attorneys for Defendant
Christopher Kyle Johnston

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PRELIMINARY STATEMENT

Defendant Christopher Kyle Johnston respectfully submits this brief in response to the Government's motion to exclude the proposed testimony of every potential expert witness that Mr. Johnston disclosed pursuant to Federal Rule of Criminal Procedure 16, ECF No. 226 ("Gov. Br."): (1) Fred H. Mills, Jr.; (2) Dr. Matthew C. Lee; (3) Mark Newkirk; (4) David S. Joseph; and (5) Carol Weinman. As set forth in five expert disclosure notices, Mr. Johnston may offer the expert testimony of each of these experts on issues beyond the ken of the average juror—including, for example, the propriety of certain compounding pharmacy practices and the respective roles and responsibilities of pharmacists and doctors in prescribing and then filling prescriptions for compounded medications. The operations and practices of a specialized compounding pharmacy and associated terminology are, as detailed herein, the foundation of Central Rexall's business, and according to the Government, the means by which the fraud was conducted—all of which are at the core of this case. The Government's motion nevertheless seeks to exclude the entirety of all five noticed experts' testimony on the grounds that each of the five disclosure notices fails to conform to the requirements of Federal Rule of Criminal Procedure 16 by insufficiently explicating each experts' "opinion," and further that each of these "opinions . . . relate to matters that are not at issue in this case, fail to address the facts of this case, or fail to demonstrate how the expert's testimony would assist the jury in deciding a matter at issue in this case." Gov. Br. at 1.

These arguments fail for two reasons. *First*, the Government incorrectly characterizes the disclosed opinions of all five noticed experts as too "generic," Gov. Br. at 10, 11; "barebones," *id.* at 7; or lacking in "actual opinions," *id.* at 13. But in fact, each of the disclosures sets forth specific, elaborated opinions on matters at issue in this case in full compliance with Rule 16 as amended. Indeed, the Government's briefs both here and in its pending motions *in limine*, ECF No. 221, repeatedly belie its own argument that the disclosures fail to provide adequate notice as to the

substance of the proposed testimony; that is, the Government's arguments that these opinions lack sufficient "fit" with the matters at issue in this trial, Gov. Br. at 1, or are "irrelevant" under Federal Rules of Evidence 401 and 403, ECF No. 221 at 48-51, demonstrate that it is clearly on notice as to the opinions that the defense experts would proffer. Moreover, each expert's specialized expertise in pharmacy and pharmaceutical industry-specific subjects—as also set forth in each disclosure—uniquely position each to assist the trier of fact in this matter to understand key terminology and practice relevant to the charges here, concepts which are decidedly beyond common knowledge. And Mr. Johnston has, for each expert, provided ample "bases and reasons" for their disclosed opinions within the meaning of Rule 16. Additionally, Ms. Weinman's specialized experience as a Applied Behavior Analysis ("ABA") Behaviorist will assist the jury in providing important context for Mr. Johnston's actions as an individual diagnosed with Autism Spectrum Disorder ("ASD").

Second, as to whether the substance of each experts' disclosed opinions is reliable and "fits" the case, the Government intentionally, but disingenuously, oversimplifies the nature of the charges it has brought in an attempt to narrow the scope of what is relevant to and at issue in this criminal prosecution. In doing so, it seeks to prohibit expert testimony about the core business of the pharmacy managed by Mr. Johnston merely because he is not a pharmacist, despite the Indictment plainly alleging that he directed the activities of pharmacists, Ind., ¶ 14, and the Government's disclosed pre-marked exhibits containing hundreds of documents regarding the day-to-day operations of the pharmacy and its pharmacists, including with regard to compounded medication, pre-printed prescription pads, and test adjudications. In short, the Government suggests throughout the Indictment that there is something insidious about the way in which this compounding pharmacy was run, but now seeks to preclude testimony by experts in that very field

that would assist the jury in understanding common and appropriate practices at just such a compounding pharmacy. And to be sure, courts in this District and elsewhere have agreed: the purported "means" and components of the scheme alleged here—specifically "compounded medications," "preprinted prescription pads," "test adjudications," and the roles of and interplay between prescribing physicians, compounding pharmacists, and Pharmacy Benefits Managers ("PBM")—are simply not within the ken of the average juror. *See, infra* Sec. II.B.1-5.

As to the expert testimony of Dr. Weinman, the Government is incorrect that Ms. Weinman proposes to provide impermissible opinion evidence about Mr. Johnston's willfulness, as her expert disclosure clearly states. Gov. Br. at Ex. 5 (ECF No. 226) ("Weinman Discl."). Nevertheless, Mr. Johnston acknowledges that her testimony may not be necessary, should the characteristics underlying her disclosed opinions not surface in the Government's case-in-chief. Thus, while the testimony of the other expert witnesses is clearly relevant to this case and should be admitted, the motion to preclude Ms. Weinman's testimony should be determined after the conclusion of the Government's case-in-chief.

I. LEGAL STANDARD

A. FEDERAL RULE OF CRIMINAL PROCEDURE 16

Federal Rule of Criminal Procedure 16 governs the form and substance of expert disclosures. Per the Rule's 2022 amendments, the relevant provision applicable to a defendant's disclosure provides:

> (C) Expert Witnesses.
>
> . . .
>
> (iii) Contents of the Disclosure. The disclosure for each expert witness must contain:
>
> - a complete statement of all opinions that the defendant will elicit from the witness in the defendant's case-in-chief;
> - the bases and reasons for them;
> - the witness's qualifications, including a list of all publications authored in the previous 10 years; and
> - a list of all other cases in which, during the previous 4 years, the witness has testified as an expert at trial or by deposition.

F.R.C.P. 16(b)(1)(C)(iii). Although the Rule requires that a party provide "a complete statement" of the witness's opinions, as the Advisory Committee Notes make clear, the Rule, even as amended, was never intended to render Rule 16 more akin to its civil analog—or require the kind of expert report that one sees in civil cases, in light of well-established, fundamental—and constitutional—distinctions between the two regimes:

> Although the language of some of these provisions is drawn from Civil Rule 26, the amendment is not intended to replicate all aspects of practice under the civil rule in criminal cases, which differ in many significant ways from civil cases. The amendment requires a complete statement of all opinions the expert will provide, but does not require a verbatim recitation of the testimony the expert will give at trial.

Advisory Committee Notes (2022 Amendment); *see also United States v. Mehta*, 236 F. Supp. 2d 150, 155 (D. Mass. 2002) ("The difference between the civil and criminal rules derives from the special constitutional constraints of criminal proceedings. Intuitively, discovery against a criminal

defendant raises the specter of infringing the Fifth Amendment privilege against self-incrimination.").[1]

Ultimately, Rule 16 "is 'intended to minimize surprise that often results from unexpected expert testimony, reduce the need for continuances, and to provide the opponent with a fair

[1]More generally, discovery in criminal cases remains far more limited than in civil cases. As the Second Circuit Court of Appeals articulated it:

> This distinction between federal civil and criminal procedure comports with broader differences between the civil and criminal regimes. First, federal criminal discovery is far more limited than federal civil discovery. When the federal government acts as prosecutor in a criminal case, it does not face the same mandatory disclosure regime as when it acts as plaintiff in a civil case. *Compare, e.g.*, Fed. R. Crim. P. 16(a), *with* Fed. R. Civ. P. 26. To be clear, a federal criminal defendant can compel the government to disclose specified materials simply by asking for them, *see, e.g.*, Fed. R. Crim. P. 12.1(b), 12.2, 12.3, 16(a), and certain statutory provisions and constitutional mandates require significant disclosures, *see, e.g.*, 18 U.S.C. § 3500(b); *Giglio v. United States*, 405 U.S. 150 (1972); *Brady v. Maryland*, 373 U.S. 83 (1963). But the fact remains that federal civil and criminal procedure are different, and that "unlike their civil counterparts, criminal proceedings have no extensive discovery . . . procedures requiring both sides to lay their evidentiary cards on the table before trial."

United States v. Sampson, 898 F.3d 270, 280 (2d Cir. 2018) (quoting *United States v. Pope*, 613 F.3d 1255 (10th Cir. 2010)); *see also United States v. Johnson*, 713 F.2d 654, 659 (11th Cir. 1983), *cert. denied*, 465 U.S. 1030 (1983) ("Although in civil cases litigants may be required to designate expert witnesses during discovery, see Fed. R. Civ. P. 26(b), the scope of discovery in criminal cases is significantly more restricted."); *United States v. Hancock*, 441 F.2d 1285, 1287 (5th Cir. 1971), *cert. denied*, 404 U.S. 833 (1971) (noting that "the scope of discovery in criminal prosecutions narrower than it is in civil cases"); *Mehta*, 236 F. Supp. 2d at 155 ("One way to decipher the meaning of the criminal expert discovery rules is to compare them to the civil discovery rules, which are much broader…Moreover, the civil rules allow further discovery through interrogatories and depositions; there is no such avenue under the criminal rules."). Indeed, the Advisory Committee is clear in stating when it *does* intend to draw closer parallels between language in the Federal Rules of Criminal and Civil Procedure, such as under distinct provisions of Rule 16, which set forth "work product" exceptions to the general discovery requirements. *See* Advisory Committee Notes (2022 Amendment) ("The subsections [at Rule 16(a)(2) and (b)(2)] proposed by the Supreme Court are cast in terms of the type of document involved (e. g., report), rather than in terms of the content (e. g., legal theory). The Committee recast these provisions by adopting language from Rule 26(b)(3) of the Federal Rules of Civil Procedure.").

opportunity to test the merit of the expert's testimony through focused cross-examination.'" *United States v. Hoffecker*, 530 F.3d 137, 185 (3d Cir. 2008) (quoting Advisory Committee Notes (1966 Amendment)) (affirming the trial court order barring the testimony of defendant's experts disclosed three days prior to jury selection with no explanation for the delay); *United States v. Wadley*, 2022 U.S. App. LEXIS 9068, at *12-13 (3d Cir. Apr. 5, 2022) (holding that the "District Court's extensive hearing, which previewed the Special Agents' proposed testimony to the defense, eliminated any prejudice to the defendants" such that the absence of *any* Rule 16 disclosure in that case would have been harmless). And "[p]reclusion of evidence, an extreme sanction, is not warranted when the purposes of Rule 16 are ultimately not frustrated." *United States v. Durante*, No. 11-277 (SRC), 2012 U.S. Dist. LEXIS 18846, at *7 (D.N.J. Feb. 15, 2012) (citing *United States v. Cuellar*, 478 F.3d 282, 294 (5th Cir. 2007)).

B. FEDERAL RULE OF EVIDENCE 702

An expert witness may testify in the form of an opinion or otherwise if "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Federal Rule of Evidence 702 sets forth the standard for admissibility of expert testimony. *United States v. Otero*, 849 F. Supp. 2d 425, 429 (D.N.J. 2012), *aff'd*, 557 F. App'x 146 (3d Cir. 2014). It provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Thus, Rule 702 requires consideration of the expert testimony's "qualification, reliability and fit." *United States v. King*, 2024 WL 3887274, at *13 (3d Cir. Aug. 21, 2024); *see also United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995) ("Rule 702 has three major requirements: (1) the

proffered witness must be an expert; (2) the expert must testify to scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact.").

The Court's role, then, is to act as a gatekeeper and ensure that expert testimony is both relevant and reliable. *Otero*, 849 F. Supp. 2d at 429 (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)). But that gatekeeping role "is not intended to serve as a replacement for the adversary system" which an opponent may use to "expose flawed expertise." *United States v. Mitchell*, 365 F.3d 215, 244-45 (3d Cir. 2004). "The judge as the gatekeeper may find flaws in an expert's methodology, disagree with the conclusions of the expert, and believe there are better grounds for a different conclusion but still permit the expert to testify because there are 'good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect.'" *Warren Hill, LLC v. Neptune Inv'rs, LLC*, No. 20-452, 2021 U.S. Dist. LEXIS 96450, at *7-8 (E.D. Pa. May 20, 2021) (quoting *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)); *see generally Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) ("The Rules of Evidence embody a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact."); *Daubert*, 509 U.S. at 588 (Rule 702 embraces the "liberal thrust" of the Federal Rules of Evidence). Accordingly, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. While the court therefore looks to relevance and reliability, "issues of credibility arise after the determination of admissibility," *Kannankeril*, 128 F.3d at 809-10, and ultimately, it is the jury that is tasked with making "[d]eterminations regarding the weight to be accorded, and the sufficiency of, the evidence relied upon by the

proffered expert." *Walker v. Gordon*, 46 F. App'x 691, 695 (3d Cir. 2002); *see also Kannankeril*, 128 F.3d at 807 ("The analysis of the conclusions themselves is for the trier of fact.").

The first requirement, that the proffered witness be an "expert," speaks to the witness's qualifications, which the Third Circuit has interpreted "liberally." *United States v. Xue*, 597 F. Supp. 3d 759, 766 (E.D. Pa. 2022) (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008)). A "broad range of knowledge, skills, and training qualify an expert." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). The Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications," as both the "substantive" and "formal" qualifications of an expert are viewed flexibly and on a specialty-specific basis. *Id.* Thus, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have specialization that the court considers most appropriate." *Pineda*, 520 F.3d at 244 (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)). And the Advisory Committee's notes to Rule 702 make clear that experience alone, or in conjunction with "other knowledge, skill, training or education," can provide a sufficient foundation for expert testimony. *See Kumho Tire Co.*, 526 U.S. at 156 (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000) (noting there are "circumstances where one's training and experience will provide an adequate foundation to admit an opinion and furnish the necessary reliability to allow a jury to consider it.").

As to the second requirement, the Third Circuit has interpreted reliability "to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *Pineda*, 520 F.3d at 244. Admissibility turns "on the expert's methods

and reasoning; credibility decisions arise after admissibility has been determined." *Kannankeril*, 128 F.3d at 806 (3d Cir. 1997). When examining expert testimony that is based on practical experience, rather than academic theories, "the *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable" because the reliability of testimony from a practical experience expert "depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *Xue*, 597 F. Supp. 3d 759, 766 (quoting *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000)); *see also United States v. Comite*, No. 06-70, 2006 U.S. Dist. LEXIS 92766, at *9 (E.D. Pa. Dec. 21, 2006) ("an opinion of an expert witness is admissible even if it has not gained general acceptance or been subject to peer review, although these are factors which the district judge should consider" (citing *Schneider v. Fried*, 320 F.3d 396, 406 (3d Cir. 2003)). Importantly, as articulated by the Third Circuit, "the reliability requirement must not be used as a tool by which the court excludes all questionably reliable evidence." *In re Paoli*, 35 F.3d at 744. Experts are permitted "wide latitude to offer opinions." *Daubert*, 509 U.S. at 592.

Finally, to satisfy the "fit" requirement, "the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). More specifically, for expert testimony to meet the *Daubert* "fit" requirement, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. "This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (internal quotations omitted) (citing *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)); *see also United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010) (expert testimony should be "sufficiently tied to the facts of the case [such] that it will aid the [factfinder] in resolving a factual dispute."). However, and again, consistent with the liberality of the Supreme Court's approach in

Daubert, the Third Circuit has repeatedly "expressed the view that 'the standard for this [relevancy] factor is not that high.'" *United States v. Ford*, 481 F.3d 215, 219 (3d Cir. 2007) (quoting *Lauria v. Nat'l R.R. Passenger Corp.*, 145 F.3d 593, 600 (3d Cir. 1998)); *see also In re Paoli*, 35 F.3d at 745 (noting the standard for analyzing the fit of an expert's analysis is "not that high," but "higher than bare relevance.").

II. NOTWITHSTANDING THE GOVERNMENT'S EFFORTS TO PRECLUDE THE DEFENDANT FROM PRESENTING HIS DEFENSE, THE DEFENSE EXPERT DISCLOSURES ARE MORE THAN ADEQUATE AND THE DEFENSE SHOULD BE ABLE TO PRESENT ITS PROPOSED EXPERT WITNESSES IN THE TRIAL OF THIS MATTER.

A. EACH DISCLOSURE CONFORMS TO RULE 16.

The Government points exclusively, with the exception of one order, to case law outside of this Circuit to support its argument that the five expert disclosure notices provided by the defense do not sufficiently conform to Rule 16(b)(1)(C)(iii)'s requirement that such notice contain "a complete statement of all opinions that the defendant will elicit from the witness in the defendant's case-in-chief;" and "the bases and reasons for them[.]" *See* Gov. Br. at 1-4. As emphasized by the 2022 Advisory Committee Notes, an adequately "complete statement" need not—nor could it—represent a "verbatim recitation of the testimony the expert will give at trial." That is, of course, because the precise nature and scope of a defense expert witness's testimony will rely significantly on and be responsive to evidence first elicited during the Government's case-in-chief. *See, e.g.*, *Valentino*, 2023 U.S. Dist. LEXIS 10756, at *43 (agreeing with defendant that "the admissibility of some of the expert testimony depended on the United States' case-in-chief at trial" in an order precluding certain disclosed expert opinions, and noting that either party was at liberty to re-raise that order in the course of trial).

Contrary to the Government's assertions, each individual expert's disclosure in this matter provides the opinions that each respective expert may testify to with sufficient clarity and

thoroughness to comply with Rule 16, as amended. For example, the disclosure for Fred Mills provides, *inter alia*, that he is expected to testify as to "the role and duties of a Pharmacist in Charge ('PIC'), including the responsibility to train and manage pharmacists and technicians" and to "opine that determining a particular patient's need for a compound medication is a determination that is left to the prescribing physician." Gov. Br. Ex. 1 (ECF No. 226) ("Mills Discl."). Mr. Mills is also expected to opine on test adjudications and that they are "a common and time-efficient method for determining coverage and pricing for a particular medications[.]" *Id*. Both the subjects to be addressed and the opinions to be rendered are provided; nothing else is required.

Likewise, Dr. Lee's disclosure articulates that he is expected to opine that it is the "pharmacist's duty [] to fulfill prescriptions as received unless there is a danger to the patient." Gov. Br. Ex. 2 (ECF No. 226) ("Lee Discl."). In this regard, he will state, as the disclosure makes clear, that particularly in the age of telemedicine, "a pharmacist has no way of knowing the specific details of a particular patient's medical appointment, or why a doctor may have deemed a particular course of treatment 'medically necessary.'" *id.*, and "that without … circumstantial 'red flags,' pharmacists have little reason to doubt the validity of a physician-patient relationship." *Id*. This disclosure describes his proffered testimony with more than the requisite completeness; to find otherwise would preclude Mr. Johnston from actually presenting his defense, even as it imposes discovery requirements on a defendant that the Rule does not impose and the Constitution does not allow.

Mr. Newkirk's disclosure also provides a complete statement of his forthcoming opinion should he be called as witness at trial. Thus, it makes clear what the two topics are upon which he will opine: first, he will discuss the "history and development of the compound pharmaceutical market prior to 2013, which is essential to contextualizing the normalcy and ubiquity of compound

medications, as well as the critical role such medications fulfill for patients with particular needs." Gov. Br. Ex. 3 (ECF No. 226) ("Newkirk Discl."). Importantly, this testimony will also speak to the appropriateness of pharmacies filling prescriptions, including for compounded medications, "that include products that reimburse at a profitable rate pursuant to the formulary for the relevant insurance company." *Id*. Second, Mr. Newkirk will opine as to "the interplay between PBMs, insurance companies, and independent pharmacies," and, "[c]ritically, [Newkirk] will elaborate on PBM contractual agreements and manuals that govern the relationship between PBMs and pharmacies, and explain the ways in which these instruments are drafted to maximize the profits of PBMs by disincentivizing certain otherwise appropriate conduct by doctors and, consequently, pharmacies." *Id*. This disclosure provides the Government with the complete notice required by the Rule.

Mr. Joseph's disclosure states that he is expected to opine, as he has in other recent health care fraud prosecutions involving compounded medication in this District, as to "pharmacist and pharmacy practices during the relevant time period in this matter, including the common practice of pharmacies, including compounding pharmacies, to use paper or electronic pre-printed prescription pads." Gov. Br. Ex. 4 (ECF No. 226) ("Joseph Discl."). "He will also opine as to the pharmaceutical industry's universal practice of initiating 'test claims' or 'test adjudications,' which incur no financial loss to any person or entity when test adjudications are 'cancelled,' or…not submitted as actual claims." *Id.* He is further expected to opine that "it is normal and proper for physicians to prescribe compounded medications in accordance with their professional judgment, whether or not the physician first tried to address a particular patients' medical needs with…non-compounded medication, and that compounded medications can be used as alternatives to other medications, including opioids, and are at times preferable[.]" *Id.* And he is expected to

testify that "medical necessity," though certainly important to a physician, "does not drive a pharmacy's operation or a pharmacist's decision to fill a prescription." *Id*. Again, this disclosure is more than sufficient.

Finally, Ms. Weinman's disclosure articulates that she is expected to opine regarding the conduct of individuals with ASD, and "how certain types of conduct are consistent with that diagnosis." Weinman Discl. Additionally, her testimony may explain and contextualize "certain elements of Mr. Johnston's behavior in the event that the Government seeks to show that such conduct is somehow consistent with willful wrongdoing." *Id*. Ms. Weinman may opine that "those elements of Mr. Johnston's behavior include difficulties developing, maintaining, and understanding relationships, and his ability to mask his autistic traits." *Id*. "Ms. Weinman will not, however, opine as to whether Mr. Johnston in fact held any specific mental state or belief at any specific time." *Id*. In describing both what Mr. Weinman my state on the stand, and what she will not, the defense disclosure more than fully satisfies the Rule.

Indeed, even a cursory review of the cases cited by the Government reveals the comparative thoroughness of the disclosures provided here. With respect to the order precluding expert testimony in *United States v. Bankman-Fried*, the disclosure stated simply that the expert testimony proffered by the defense "'would principally be in the nature of rebuttal testimony, which would necessarily depend on the evidence the Government presents at trial through its own fact and expert witnesses.'" No. S6 22-cr-0673 (LAK), 2023 U.S. Dist. LEXIS 168116, *2 (S.D.N.Y. Sep. 21, 2023). The court concluded that this disclosure plainly fell short of Rule 16(b)(1)(C)(iii)'s requirements in that it provided no statement of opinions, and no bases and reasons for them. *Id.* at *1-2; *see also id.* at *3 (stating, with respect to another expert noticed by defendant, that the disclosure, while including "the heading 'Scope and Summary of Opinions,'

actually contained no opinions. Rather it states that he 'may testify to the following topics.' All of the proposed topics are introduced with the phrase 'General Background on' various subjects."). As described above, the disclosures in this case bear no resemblance to those provided by the defense here.

Likewise, Judge Salas's order precluding the testimony of a proposed expert in *United States v. Schessel*, 22-cr-374 (ES), ECF No. 232 at 8-9 (D.N.J. May 3, 2024) on the basis of insufficiently specific opinions, considered a similarly vague disclosure. *See id.* at ECF No. 224-1 (D.N.J. Apr. 16, 2024) (providing a single short paragraph of the expert's proffered topics of testimony, such as, *inter alia*, "generally the filing of 10-Qs, 10-Ks, and 8-Ks, and the issuance of press releases," and "Mr. Badway will explain that publicly traded companies typically communicate with their investors through a variety of means"). And the court's order precluding expert testimony in *United States v. Biden*, 2024 U.S. Dist. LEXIS 152609 (D. Del. June 2, 2024), involved a decidedly vaguer disclosure in a prosecution for unlawful firearm possession; specifically, the expert disclosure's permissively worded "assertions"—such as, "[t]he cycles of sobriety, recovery, and rehabilitation also impact a substance abuser's view that they are not 'addicts' at any given time," *id.* at *7-8—did not put the Government sufficiently on notice as to what the actual substance of the expert's testimony would be.

The Government also cites *United States v. Ulbricht*, for the proposition that Mr. Johnston's expert disclosures fail because they do not provide "appropriate detail." No. 14-cr-68 (KBF), 2015 U.S. Dist. LEXIS 11936, at *14-15 (S.D.N.Y. Feb. 1, 2015). However, the Government ignores the facts of *Ulbricht*, which include that defendants failed to disclose their intention to call *any* expert witnesses until trial started, *id*. at *5; that their disclosures were "bare bones," *id.* at *7; and that the disclosure letters lacked any expected opinions, the bases of such

opinions, or their expertise in areas in which they seek to testify. *Id.* at 7. That is simply not the case here. Each expert disclosure was timely provided on December 6, 2024 pursuant to the pretrial scheduling order, ECF No. 195 ¶ 6, nearly two months before the start of trial. Each of those disclosures included not merely a "bare bones" list of possible topics, but specific opinions on relevant topics about which each expert would testify. Indeed, as set forth in greater detail below with respect to each expert witness, the Government's moving briefs here and in support of its motions *in limine* attack each defense expert's opinion in sufficient detail, arguing that the proposed testimony is irrelevant and citing various portions of the disclosures to highlight this point. But in doing so, the Government demonstrates a clear understanding of substance of the expert testimony, the bases for their opinions, and their areas of expertise. *See, infra*, Section II.B. (citing ECF No. 221 at 14, 16-17, 20), which it could not do were the disclosures as "cursory," "general," "barebones," "vague[]," "inadequate," or "generic," as the Government claims for each such witness. Gov. Br. at 1, 7, 11, 15, 17.

The Government also cites *United States v. Kaufman*, to argue that Mr. Johnston's expert disclosures "never sufficiently and specifically articulated the substance of each of the opinions [they] would have given." No. 19-cr-504 (LAK), 2021 U.S. Dist. LEXIS 170367, *56 (S.D.N.Y. Sep. 7, 2021). However, once again, the court in *Kaufman* considered a disclosure—the "second supplemental [] and thus third [] expert disclosure . . . halfway through trial," *id.* at *42—that was decidedly vague, general, and in fact "inconsistent" with both a separate defense expert disclosure and "with varying arguments made by defense counsel at trial." *Id.* at *45. The court ultimately found that, "[d]espite multiple rounds of expert disclosures—the last of which Kaufman submitted at the eleventh hour during trial—it is unclear exactly what Dr. Guedj's proposed opinions would have been, what his methodology (if any) had been, and how the slides he produced in response to

the government's motion *in limine* would have related to his proposed testimony." *Id.* As well, the Court concluded that "Kaufman has not proffered any meaningful analysis that Dr. Guedj would have provided … except to say generally that he had made them." *Id.* at *51.

Obviously, the opinions here suffer from none of the flaws found in *Kaufman*. To the contrary, and as discussed in greater detail in Section II.B, the expert testimony proffered by Mr. Johnston is plainly relevant, as it explains and contextualizes the industry-specific "tools" that the Government alleges Defendants used in their conspiracy, on the basis of each disclosed experts' specialized experience and professional training. *See, e.g.*, Mills Discl. (opining that "so-called 'test adjudications,' which involve claims that are never submitted for payment . . . [are] a common and time-efficient method for determining coverage and pricing for particular medications, the appropriateness of which practice may be determined by a PBM's contract with a pharmacy."); Lee Discl. (opining that preprinted prescription pads "are an effective and efficacious safeguard against handwritten and typographic or other inaccuracies and, thus, safer for patients"). And far from being confusing or misleading, the testimony will help to explain complex pharmaceutical terms and practices at issue in this case, as well as the relationships between both doctors and pharmacies and PBMs and pharmacies. *See, e.g.*, Lee Discl. (opining that "in the age of telemedicine, a pharmacist has no way of knowing the specific details of a particular patient's medical appointment, or why a doctor may have deemed a particular course of treatment 'medically necessary;' indeed, a pharmacist's duty is to fulfill prescriptions as received unless there is a danger to the patient."); Mills Discl. (opining that "compounding pharmacies must meet certain FDA standards…and elaborate on the consistencies among different states' pharmaceutical regulations in that regard."); Newkirk Discl. ("Newkirk will elaborate on PBM contractual agreements and manuals that govern the relationships between PBMs and pharmacies, and explain

the ways in which these instruments are drafted to maximize the profits of PBMs by disincentivizing certain otherwise appropriate conduct by doctors and, consequently, pharmacies.").

Finally, the Government cites *United States v. Dzionara-Norsen* for the proposition that this Court should exclude Mr. Johnston's proposed autism expert for having "limited educational or practical experience supporting his purported expertise." No. 21-454-cr, 2024 U.S. App. LEXIS 1144, at *10 (2d Cir. Jan. 18, 2024). But that case is not analogous: Ms. Weinman is an attorney who specializes in autism expert consulting in the legal field, as well as an Autism Behavior Consultant. She holds numerous certifications and a wealth of experience in the study of autism. Specifically, she is a Certified Autism Specialist, per the International Board of Credentialing and Continuing Education Standards; she serves on the Advisory Board for the U.S. Autism Association, and is a Board Member of The Autism and Asperger Alliance for Greater Philadelphia. Along with her certifications and board positions all in the field of Autism, Ms. Weinman has spoken at countless Autism conferences, serving as both an expert and keynote speaker in these speaking engagements. She also is hired to provide trainings and CLEs to criminal defense attorneys and public defenders offices. *See* Weinman Discl. ("The Autistic Client, 2024" and "CLE: Understanding the Autistic Client, 2024."). Thus, unlike the expert in *Dzionara-Norsen*, Ms. Weinman possesses far more than a "limited educational or practical experience supporting [her] purported expertise." *Dzionara-Norsen*, 2024 U.S. App. LEXIS 1144, at *10. And aside from her experience, Ms. Weinman's expert witness disclosure was as specific as possible given the current phase of this litigation. *See Valentino*, 2023 U.S. Dist. LEXIS 10756, at *43 (admissibility of some expert testimony "depended on the United States' case-in-chief at trial"). Based on what counsel currently knows about the Government's intended presentation,

Ms. Weinman will testify regarding "those elements of Mr. Johnston's behavior include difficulties developing, maintaining, and understanding relationships, and his ability to mask his autistic traits. It may also include general isolating behaviors, hyper-focus on specific individual issue or person and excessive garrulousness," Weinman Discl., all traits that may become relevant at trial (if, for example, the Government seeks to draw inferences from the length phone conversations, as set forth in telephone records). However, as stated above and in her disclosure, she will not "opine as to whether Mr. Johnston in fact held any specific mental state or belief at any specific time." *Id*. That said, counsel will of course supplement this disclosure as required to the extent more is learned about the Government's opening and case-in-chief, which (as the Government was informed) will determine whether or not Ms. Weinman will actually be called. *Cf. United States v. Robinson*, 258 F. Supp. 3d 85, 87 (D.D.C. 2017) (the district court allowed the previously disclosed defense expert "to supplement the disclosure by presenting [the expert] to describe his additional opinions orally at the [] *Daubert* hearing[.]").

In sum, each expert's disclosure complies sufficiently with Rule 16's requirements. Indeed, as discussed in Sec.II.A, *infra*, the Government's arguments with respect to each individual disclosure's substance reveals the Government's clear understanding (and disagreement with) the opinions that each expert has proffered.

B. EACH DISCLOSED OPINION IS RELIABLE AND RESPONDS TO, AND FURTHER CONTEXTUALIZES, CRITICAL SUBJECTS THAT THE GOVERNMENT HAS PLACED AT ISSUE IN THIS CASE.

As a threshold matter, the Government does not challenge Mr. Mills, Dr. Lee, Mr. Newkirk, or Mr. Joseph's qualifications to testify as expert witnesses.[2] Instead, the Government, in cursory

[2]Indeed, David Joseph and Mark Newkirk have both been admitted as expert witnesses in similar federal prosecutions, including that Mr. Joseph recently testified in a similar vein in a case in this District, over which Judge Arleo presided. *See Andrews, et al.*, 2:20-cr-578-MCA at ECF No. 163 (admitting expert testimony by Mr. Joseph regarding pharmacological-specific practices,

fashion, asserts that the opinions to which those four experts will testify are not reliable and do not "fit," or, in other words, are irrelevant to this case. *See* Gov. Br. at 8, 10, 11, 12, 13, 15, 16, 17, 19 (citing *Daubert*, 509 U.S. at 591; Fed. R. Evid. 702). But as explained below with respect to each expert in turn, the face of the Indictment plainly reveals that the opinions described in each of these experts' disclosures are in fact directly relevant to the Government's theory of the case. And the Government's submissions to this Court and pre-marked exhibits further support the admission of these expert witnesses.

Moreover, cases in both this and other Circuits, similar to the instant matter and brought under the same statutes charged here, reveal that expert witnesses testimony on the specialized, pharmacological industry-specific topics that are contemplated in these experts' disclosures, are routinely offered by both the Government and the defense and are commonly admitted. Indeed, the opinions of two of the proposed expert witnesses here have either gone unopposed or been admitted over the Government's objections within just the past year in cases alleging health care fraud, including those involving compounded medication prescriptions. *See, e.g.*, *United States v. Andrews, et al.*, 2:20-cr-578-MCA at ECF No. 163 (D.N.J. Oct. 24, 2024) (denying Government's motion to preclude expert testimony of David Joseph in case charging health care fraud on the basis of compounded medication prescriptions and "reserv[ing] decision as to whether Mr. Joseph . . . is precluded from offering certain opinions . . . regarding efficacy of compounded medications"); *United States v. Mokbal*, 4:21-cr-103-LHR at ECF No. 151 (S.D. Tex. Apr. 15, 2023) (Government did not seek to preclude defendant's noticed expert Mark Newkirk, also

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including the background of compounded medication); *United States v. Blair*, No. ELH-19-00410, 2021 U.S. Dist. LEXIS 209378 (D. Md. Oct. 29, 2021) (admitting expert testimony by Mr. Joseph regarding use of test claims by pharmacies); *United States v. Mokbal*, 4:21-cr-103-LHR at ECF No. 151 (S.D. Tex. Apr. 15, 2023) (Government did not oppose defendant's motion *in limine* to admit Mr. Newkirk as an expert).

noticed by Mr. Johnston in the instant matter, in a case charging health care fraud); *see also United States v. Chalker*, 966 F.3d 1177, 1186 (11th Cir. 2020) (in health care fraud prosecution, describing Government's noticed expert witness in "pharmacy operations" as having testified regarding compounded medications); *United States v. Valentino*, No. 20-309, 2023 U.S. Dist. LEXIS 10756, at *44-45 (E.D. Pa. Jan. 23, 2023) (discussing the tailoring of defendant's expert witness's testimony in a health care fraud prosecution to "expert testimony about what compound pain creams are, how they are prescribed and dispensed, the use of e-scribing to prescribe, the need to send such prescriptions to 'specialty' compounding pharmacies as opposed to a local pharmacy . . . which may require prescriptions to be mailed, and very briefly the need for physicians to prescribe medication to an 'in-network' pharmacy."); *United States v. Blair*, No. ELH-19-00410, 2021 U.S. Dist. LEXIS 209378, *51-52 (D. Md. Oct. 29, 2021) (in a case charging health care fraud, denying defendant's motion to exclude Government's noticed expert's testimony as to definitions of, *inter alia*, "prescribing practices," "medical necessity," and explications as to when "compounded medications" may be prescribed, finding that "the topics clearly constitute relevant information that would be helpful to the jury. For example, the case concerns the prescriptions of compounded substances. To challenge testimony about the nature of compounding, its purposes, the circumstances for which such drugs are warranted, and prescription practices [] strains credulity."). As set forth below, on a witness-by-witness basis, they should be allowed here as well; indeed, to preclude them would interfere with Mr. Johnston's fundamental right to present a defense to the charges that he faces. *Holmes v. South Carolina*, 547 U.S. 319, 324 (2006) ("Whether rooted directly in the Due Process Clause of the Fourteenth Amendment or in the Compulsory Process or Confrontation Clauses of the Sixth Amendment, the Constitution guarantees criminal defendants 'a meaningful opportunity to present a complete defense.'").

1. Fred H. Mills, Jr.

As discussed above, Mr. Mills is expected to testify regarding: a PIC's responsibilities to train and manage pharmacists and technicians; compounding pharmaceuticals and the requirement that they need to meet certain FDA standards; and the patient's need for compound medication is a determination left to the prescribing physician. Mills Discl. He is also expected to opine regarding PBMs, their relationship with pharmacies, the features of the PBM's contracts with pharmacies and insurers, and "test adjudications." *Id.* The Government, however, seeks the extraordinary remedy of precluding this testimony, arguing that Mr. Mills testimony is primarily about general topics, not containing any proposed opinions about the Defendants or Central Rexall, therefore "leav[ing] the government in the dark as to what his opinions" will be, or that they are not relevant. Gov. Br. at 9. These argument, purportedly based upon "fit," boil down to the notion that because Mr. Mills does not propose to testify exclusively as to norms and practices at Central Rexall—in other words, the kind of lay witness testimony the Government suggests it will elicit from "*actual* Central Rexall witnesses"—it is irrelevant to this case. *Id.* The Government's argument relies both on a patent oversimplification of the topics at issue in this case, such as "test adjudications," prescribing "compounded medications," and "preprinted prescription pads"—which its "*actual* Central Rexall witnesses" are not claimed to have the training and/or specialization to accurately or helpfully contextualize and explicate to jurors. It also reflects a fundamental misunderstanding of the purpose and scope of the type of testimony defense experts could provide under Rule 702, based on their experience, as distinguished from lay or fact witness testimony. *See Wadley*, 2022 U.S. App. LEXIS 9068, at *12 ("[T]he distinction between lay and expert witness testimony is that lay testimony results from a process of reasoning familiar in everyday life, while expert testimony results from a process of reasoning which can be mastered only by specialists in the field.") (quoting Fed. R. Evid. 701 Advisory Committee Notes (2000

Amendment)); *United States v. Trotter*, No. 14-20273, 2017 U.S. Dist. LEXIS 150806, at *21 (E.D. Mich. Sep. 18, 2017) ("Expert testimony, unlike lay testimony, relies on 'scientific, technical, or other specialized knowledge within the scope of Rule 702.' Fed. R. Evid. 701."). Specifically, key industry-specific terminology that the Government identifies as an aspect of the "manners" and "means" of the charged conspiracy throughout the Indictment—including, *inter alia*, "test adjudications," "compounded medications," "Pharmacy Benefits Manager," and "medical necessity," *see* Ind., ¶¶15-41—are simply not commonly known or understood terms and, without explication, will likely be familiar to the jury. That is explicitly evidenced by case law admitting both defense and Government expert witnesses on these very topics in several health care fraud prosecutions both in and outside of this Circuit. *See Andrews, et al.*, 2:20-cr-578-MCA at ECF No. 163; *Chalker*, 966 F.3d at 1186; *Blair*, 2021 U.S. Dist. LEXIS 209378, *51-52; *Valentino*, 2023 U.S. Dist. LEXIS 10756, at *44-45; *Mokbal*, 4:21-cr-103-LHR at ECF No. 151. Mr. Mills will, as discussed in his disclosure, assist the jury by explaining just these technical concepts. Mills Discl.

Nevertheless, the Government first argues that Mr. Mills's proposed opinions on "test adjudications" "do[] not fit this case and will not be helpful to the jury because he offers no opinions about the specific test adjudications that were actually done in this case." *Id.* But while the Government has every right to cross-examine Mr. Mills on this topic and to argue that his opinion accordingly deserves little weight, it does not determine whether his testimony on this subject is admissible under Rule 702. Specifically, "test adjudications" are plainly relevant to the charges the Government has brought in this matter; specifically, the Indictment alleges that "[i]t was … part of the conspiracy that in order to determine the insurance adjudication for a potential new combination of ingredients . . . [the Defendants] caused Central Rexall employees and

contractors to submit to Pharmacy Benefits Administrator false test claims ('test adjudications'), which were false and fraudulent because the test adjudications necessarily represented that Central Rexall had received a valid prescription[.]" Ind., ¶25. Indeed, an entire section of the Government's brief in support of its motions *in limine* is dedicated to "Submitting fraudulent test claims" and details "how the scheme worked," discussing test claims, their purpose, and how defendants were involved. *See* ECF No. 221 at 16-17, 20.

The Government has thus clearly injected the notion that "test adjudications," as that term is used in the medical insurance and pharmacological industries, are synonymous with "false test claims," while providing its own definition of what such "test adjudications" entail, how they are normally submitted, and how that practice was or was not followed at Central Rexall. *Id.* It is this definition and argument about what normally occurs that Mr. Mills seeks to address; the "fit" between his proposed testimony and the Government's theory of prosecution is thus manifest. Nor is it required that his testimony address every aspect of the Government's theory, *i.e.*, what the practice was at Central Rexall. *See, e.g.*, *United States v. Weir*, No. 2:21-cr-00008, 2023 U.S. Dist. LEXIS 178953, at *8-9 (M.D. Tenn. Oct. 4, 2023) (denying Government's motion to preclude defense expert's testimony regarding "the historical role of small pharmacies," which the court found "well within [the expert's] expertise and relevant to the case," contrary to the Government's argument that it "could not be relevant to [defendant's] state of mind," as "[o]ne of the issues that the jury will likely have to consider is whether the defendants' actions toward patients revealed an eagerness for those patients' business that was more indicative of a money-making scheme than a pharmaceutical practice").

Specifically, Mr. Mills's disclosure makes clear that he will opine that "so-called 'test adjudications,' which involve claims that are never submitted for payment . . . [are] a common and

time-efficient method for determining coverage and pricing for particular medications, the appropriateness of which practice may be determined by a PBM's contract with a pharmacy." Mills Discl. In other words, Mr. Mills's proposed opinion on the topic of "test adjudications" will contextualize and challenge the Government's allegations regarding what "test adjudications" are and what they may be used for, both critical issues in this case. There is, moreover, no indication whatsoever that any "*actual* Central Rexall witnesses" the Government suggests it will call, Gov. Br. at 9—while they may be able to discuss what the practices were at Central Rexall—could testify as to what "test adjudications" are in general, or be in a position to provide the kind of helpful and contextualizing expert testimony that the Government has, by its own allegations, made necessary here. *Blair*, 2021 U.S. Dist. LEXIS 209378 at *88 (district court permitted expert to testify about the use of test claims by pharmacies). To the extent the Government argues that expert opinions on PBMs are likewise irrelevant where they may relate to "*other* actors in the PBM industry" rather than constituting "case-specific evidence," *id.*, it is clear both from the Indictment's allegations and from Mr. Mills's disclosed opinions that it is impossible to adequately define certain key concepts alleged to be components of the fraud charged in this case—here, specifically "test adjudications"—without describing what a PBM is, and what its role is with respect to pharmacists fulfilling and seeking reimbursement for prescriptions.

The Government further argues that Mr. Mills's disclosed opinions regarding "the roles, duties, and professional obligations of a . . . PIC" do not "'fit' this case" simply because "neither Johnson nor Brockmeier was a PIC." Gov. Br. at 8. As clearly set forth in his disclosure, Mr. Mills will opine that a PIC's duties "include[e] the responsibility to train and manage pharmacists and technicians[,]" and that a PIC's "professional obligations [] [are] dictated by state-level codes of ethics." Mills Discl. This is directly relevant to fundamental components of the Government's

prosecution; specifically, by alleging that Defendants supervised and directed pharmacists to engage in certain acts, the Government effectively seeks to impose on Defendants professional duties in fact belonging to PICs, PBMs, and prescribing physicians[3]—duties whose nature and interplay, as with the function of "test adjudications," are unequivocally beyond the average juror's common knowledge. For example, the Government's allegations clearly support the wholly inaccurate notion that Defendants had some measure of say in determining the "medical necessity" of certain prescribed medications with respect to specific patients, *see, e.g.*, Ind., ¶ 30 ("It was further part of the conspiracy that . . . at the direction of defendants . . . Central Rexall developed a different combination of ingredients based on the amount that insurance would pay for that combination rather than the medical necessity or effectiveness of the new combination of ingredients"). Similarly, the Government's allegations effectively ascribe the roles and duties of a compounding pharmacist to Defendants, suggesting that Defendants themselves were responsible for formulating prescribed compounded medications received by certified Central Rexall pharmacists from physicians. *See* Ind., ¶ 24 ("It was further part of the conspiracy that defendants . . . designed combinations of ingredients for compounded medications based on the combinations' high insurance reimbursements and manipulated the ingredients to obtain the highest possible insurance reimbursement rather than to serve the medical needs of patients."); *id.* at ¶ 28 ("It was further part of the conspiracy that defendants . . . used the information from these test adjudications to design compounded medications based on the amount of money that insurance

[3]These duties are, in fact, determined by "state-level codes of ethics," as well as "FDA standards" and "different states' pharmaceutical regulations," all of which Mr. Mills will opine on as detailed in his disclosure. Mills Discl. Thus, contrary to the Government's argument that these specific opinions testimony "will not help the jury resolve any factual issue in this case," Gov. Br. at 8, a basic, high level treatment of these regimes is necessary to accurately testify as to the roles and responsibilities placed at issue by the Government's allegations.

would pay for the compounded medications rather than on the medications' ability to help patients."). Mr. Mills's testimony would counter these allegations by describing, at a high level, the regulatory regimes and attendant duties and responsibilities ascribed to the professionals involved in prescribing compounded medications, namely: PICs, who are responsible for "train[ing] and manag[ing] pharmacists and technicians"; prescribing physicians, who determine a "particular patient's need for a compounded medication," and whose determination in that regard "may include a particular medication's availability and/or price"; and PBMs, whose individual contracts may determine "the appropriateness" of paying for a particular medication at a particular rate, including whether and how a particular pharmacy may use "test adjudications." Mills Discl.

Finally, contrary to the Government's argument that Mr. Mills's testimony would be unreliable because he "has failed to explain . . . what methods he used to reach his opinion, or what bases he has for his opinion other than his subjective beliefs," Gov. Br. at 10, Mr. Mills's disclosure specifically lays out that:

> These opinions are based on Mr. Mills's years of experience as a pharmacist, owner of Mills Cashway Pharmacy (a compounding pharmacy), former executive director of the Louisiana Board of Pharmacy, and as a state legislator who actively advocated for and assisted in enacting legislation applicable to PBMs and the pharmaceutical industry. Mr. Mills received a bachelor of science degree in pharmacy from the University of Louisiana at Monroe.

Mills Discl. As the disclosure relating to Mr. Mills describes, these are the bases for Mr. Mills's opinions *in this* case, supplemented as they are in that disclosure with a thorough description of Mr. Mills's credentials and his professional background, as well as with his attached curriculum vitae. *See id.* And, of course, these sorts of credentials may suffice to qualify a witness as an expert. *See* Rule 702 Advisory Committee Notes (providing that experience alone, or in conjunction with "other knowledge, skill, training or education," can provide sufficient foundation for expert testimony); *Kumho Tire Co.*, 526 U.S. at 156 ("no one denies that an expert might draw

a conclusion from a set of observations based on extensive and specialized experience"). Mr. Mills's proffered expert testimony is thus reliably grounded in extensive industry experience, as well as being critical to assisting the jury to understand the key issues in this case.

2. Dr. Matthew C. Lee, MD, R.Ph, MS, ABIME

Dr. Lee's testimony, as the defense has disclosed, will address relationships between pharmacists and doctors, the reasonableness of a pharmacist to doubt the validity of a physician-patient relationship, the use of pre-printed prescription pads, and a pharmacist's duty to fulfill a prescription. Lee Discl. The Government however argues that a number of these topics are irrelevant. But this requires ignoring certain fundamental aspects of the conspiracy—for example, the use of "preprinted prescription pads." But again, the Government has directly placed each of the issues about which Dr. Lee will opine before the Court and the jury. Specifically, with regard to "pre-printed prescription pads," on which the supposedly fraudulent prescriptions filled by pharmacists at Central Rexall were set forth, the Indictment alleges that "[i]t was further part of the conspiracy that at the direction of defendants . . . Central Rexall used preprinted prescription pads with their formulas for compounded medications." Ind., ¶ 21; *see also id.* at ¶ 29 ("It was further part of the conspiracy that under the direction of defendants . . . Central Rexall placed compounded medication combinations on its prescription pads and sent compounded medications to patients . . ."). And the Government's motions *in limine* further describe how these topics will be issue in the trial. ECF No. 221 at 14 ("Central Rexall gave out the outside sales representatives preprinted prescription pads that listed compound medication formulas that the defendants had determined would net Central Rexall high reimbursements…"); *id.* at 17 ("…the formulae would be placed on Central Rexall's preprinted prescription pads and distributed…").

In providing a basic description of "preprinted prescription pads," and proposing to opine that they "are an effective and efficacious safeguard against handwritten and typographic or other

inaccuracies and, thus, safer for patients," Lee Discl., Dr. Lee's testimony will explicitly address the Government's transparent attempt to characterize the very use of "preprinted prescription pads" as somehow inherently insidious, *see* Ind., ¶ 21. To the extent the Government, in the instant motion, suggests that the benefits of using preprinted prescription pads, as suggested by Dr. Lee's disclosed opinion, are "bland truisms that will not assist the jury in deciding the issues in this case," Gov. Br. at 12, that directly contradicts clear suggestions to the contrary in the Indictment and its motion *in limine*, and unreasonably assumes that the basic idea of what a preprinted prescription pad even is, is somehow common knowledge. As other courts have held, it is not. *See, e.g.*, *Valentino*, 2023 U.S. Dist. LEXIS 10756, at *44-45 (permitting defendant's expert witness to testify to "the use of e-scribing to prescribe"); *Blair*, 2021 U.S. Dist. LEXIS 209378, *51-52 (permitting the Government's expert witness to testify as to "prescribing practices"); Ind., ¶ 21; *see also id.* at ¶ 29 ("It was further part of the conspiracy that under the direction of defendants . . . Central Rexall placed compounded medication combinations on its prescription pads and sent compounded medications to patients . . .").

Likewise, while the Government concedes that "red flags" pertinent to filling certain prescriptions "will be an issue in this case," it argues that Dr. Lee's disclosure "does not contain any opinions about this matter[.]" Gov. Br. at 11. In fact, the disclosure provides that:

> Dr. Lee is expected to testify that, while a pharmacist may in accordance with his or her professional experience find certain facets of a particular prescription worthy of further investigation—for instance, an especially high dose of certain controlled substances, or an inexplicably long distance between a prescribing doctor's office and the pharmacy—such "red flags" are highly context-specific.

Lee Discl. This expert testimony will, then, go directly to what the role of the pharmacist is and can be in terms of filling prescriptions that are provided by doctors. And, to the extent the Government, again, argues that "*defendants are not pharmacists*," Gov. Br. at 12 (emphasis in original), this in some ways, is the very point: the Government's theory is that the defendants were

directing pharmacists to do that which they should not have, which in turn, demands that the duties of pharmacists be explained to the jury, rather than assumed. That is, the Indictment, in a number of places, alleges that Central Rexall staff were "directed" to facilitate the purported fraud by Defendants, placing the question of certain pharmacological and medical industry norms, as well as the roles and responsibilities of pharmacists, directly at issue. *See, e.g.*, Ind., ¶ 19 ("It was further part of the conspiracy that the effect of these agreements with PMG and Bluen Medical was to give defendants . . . power to manage the operations of Central Rexall"); *id.* at ¶ 25 ("It was further part of the conspiracy that in order to determine the insurance adjudication for a potential new combination of ingredients . . . defendants . . . caused Central Rexall employees and contractors to submit to [PBA] false test claims"); *id.* at ¶ 30 ("It was further part of the conspiracy that . . . at the direction of defendants . . . Central Rexall developed a different combination of ingredients based on the amount that insurance would pay for that combination rather than the medical necessity or effectiveness of the new combination of ingredients").

Similarly, one of the other cruxes of the alleged scheme is that patients received prescriptions although they were not examined by a doctor or other medical professional. Ind., ¶ 34; *see also* ECF No. 221 at 14 and 18. In connection with this allegation, the Government seeks to highlight "red flags," such as the distance between patients and prescribers that "should" have caused the pharmacy to question the validity of the prescription or the bona fides of the physician-patient relationship. Thus, it is important for Dr. Lee to assist a jury in understanding the duties and role of pharmacists in filling prescriptions, and the extent to which pharmacists should be questioning patient-doctor treatment discussions and determinations. In particular, as summarized in his disclosure, Dr. Lee's expert testimony is proposed in order to help explain that, particularly following the advent of telehealth, a pharmacist has no way of knowing a particular patient's

medical needs, leaving the "medical necessity" treatment analysis to fall to a prescribing physician, not the pharmacy. While the Government says this is "of course both true and irrelevant," Govt. Br. at 11, the latter cannot be the case as the Government's entire theory is that the prescriptions here at issue were "false and fraudulent" because they were "for medically unnecessary … compounded prescription medication." Indictment, ¶ 14. If that is the Government's theory, then expert testimony that this is a call that doctors—and not pharmacists or those who manage pharmacies—make, is critical to the defendants' right to present a defense.

The Government also posits that Dr. Lee's "disclosure statement [] lacks a meaningful description of the 'bases and reasons' for his opinions," and is therefore unreliable. Gov. Br. at 10. But Dr. Lee's disclosure, in addition to providing his curriculum vitae, makes clear exactly what the basis for his opinions are:

> These opinions are based on Dr. Lee's approximately thirty years of experience as a medical professional, working as a licensed pharmacist, doctor, and medical examiner at a variety of medical practices and pharmacies.

Lee Discl. As set forth above, this is sufficient, as a matter of law. And that background is necessary so that the jury may hear, contrary to the Government's effort to conclusorily label this matter as "a fraud case about how the non-pharmacist defendants orchestrated a vast conspiracy to defraud health care benefit programs[,]" Gov. Br. at 12, that this case is in fact one that requires the jury to grapple with a number of industry-specific jargon and concepts which are integral to the charges the Government has brought. The Government's effort to pretermit the defense in the case should not be allowed just because it claims that "the jury does not need an expert to" explain these ides. Gov. Br. at 11. Dr. Lee's testimony should appropriately be admitted here.

3. Mark Newkirk, PharmD

Mark Newkirk has been offered as an expert to testify, pursuant to his disclosures, about the history and development of the compounding pharmaceutical market, "contextualizing the

normalcy and ubiquity of compounded medications, as well as the critical role such medications fulfill for patients with particular needs." Newkirk Discl. He will also opine as to the relationship between PBMs, insurance companies, and independent pharmacies. *Id.* The Government, however, argues that, because "this case is about a conspiracy that started in July 2013," Mr. Newkirk's expert opinions as to "the history and development of the compounded pharmaceutical market prior to 2013" are "not relevant and will not assist the jury." Gov. Br. at 13-14. Nevertheless, the Indictment's cursory definition of compounded medications, *see* Ind., ¶¶ 2-4, and clear attempts to paint these substances as inherently unsafe, ineffective and/or of inferior quality certainly necessitate accurate contextualization. *See, e.g.*, Ind., ¶ 3 ("the FDA does not verify the safety, effectiveness, or quality of compounded drugs."); *id.* at ¶ 35 ("Central Rexall promoted Central Rexall compounded medications as prescription treatments for medical conditions and weight loss without tests or studies to support the claims"); *id.* at ¶36 ("It was further part of the conspiracy that Central Rexall marketing materials and communications with patients falsely represented that Central Rexall compounded medications were costume designed to suit the medical needs of individual patients."). To that end, as disclosed, Mr. Newkirk would opine as to the "normalcy and ubiquity of compounded medications, as well as the critical role such medications fulfill for patients with particular needs," necessitating at least some limited background as to the development of compounded medications. Newkirk Discl. Such testimony has been allowed in other cases, including in this District; *see Andrews, et al.*, 2:20-cr-578-MCA at ECF No. 163 (admitting, over Government objection, the trial testimony of David Joseph, also offered here, on *inter alia*, the history of compounding); *Blair*, 2021 U.S. Dist. LEXIS 209378, *51-52 (admitting expert's testimony regarding, *inter alia*, "prescribing practices," "medical necessity," and explications as to when "compounded medications" may be prescribed, finding

that "the topics clearly constitute relevant information that would be helpful to the jury . . . [where] the case concerns the prescriptions of compounded substances."); *Valentino*, 2023 U.S. Dist. LEXIS 10756, at *44-45 (admitting defendant's expert witness's testimony "about what compound pain creams are, how they are prescribed and dispensed, the use of e-scribing to prescribe, the need to send such prescriptions to 'specialty' compounding pharmacies as opposed to a local pharmacy").

The Government next argues that Newkirk's proposed testimony regarding the "general interplay between all PBMs, insurance companies, and independent pharmacies is simply not at issue in this case." Gov. Br. at 14. Again, the Indictment and the Government's motion *in limine* contradict this argument. *See, e.g.*, ECF No. 221 at 15-16 ("…overseeing the manipulation of Central Rexall's compound medication formulas to include ingredients only because PBMs would cover and reimburse them"); *id.* at 16 ("At times when PBMs stopped covering ingredients that were abused by compounding pharmacies, Central Rexall substituted other ingredients…"); *id.* ("this new 'test' or 'dummy' claim looked to the PBM just like a legitimate claim…"); *id.* at 30 ("…Central Rexall's practices of paying volume-based commissions….exposed [them] to audits by the PBMs…"). Additionally, the Government argues "[t]he jury will hear evidence about a particular pharmacy (Central Rexall) and the specific claims it submitted to the PBA and other PBMs[.]" Gov. Br. at 14. Clearly, the interplay between PBMs and independent pharmacies are central to this prosecution. Rather than "confuse" the jury, as the Government suggests it would, Gov. Br. at 12, Newkirk's proposed testimony would assist it to understand that interplay, including how and why the PBMs conducted audits and stopped covering ingredients, and the nature of the contractual relationships between pharmacies, like Central Rexall, and PBMs, like Express Scripts, the PBM here.

The Government finally argues, as it does throughout (always in summary fashion), that "Newkirk has not explained what reliable methodology he has used to reach his opinions or what supports his opinions other than his subjective beliefs." Gov. Br. at 15. As the law makes clear, however, the reliability of testimony from a practical experience expert "depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *Xue*, 597 F. Supp. 3d 759, 766 (quoting *Hankey*, 203 F.3d 1160 at 1169); *see also Kumho Tire Co.*, 526 U.S. at 156 (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience"). And, with that law in mind, the notion that Mr. Newkirk's disclosure does not adequately articulate his "bases and reasons" under Rule 16 is belied by the disclosure, which, in addition to Mr. Newkirk's curriculum vitae, states that:

> These opinions are based on Mr. Newkirk's work for over 27 years in the pharmaceutical industry and thirteen years' experience as a field auditor for one of the largest pharmacy benefit companies in the country. As a senior field auditor, Mr. Newkirk travelled extensively across the country performing in-depth audits of pharmacy claims in thousands of retail, hospital, long-term care, compounding and specialty pharmacies. Mr. Newkirk then spent three years working as a mail order pharmacist and manager for the largest PBM in the country. After his work in auditing and as a registered pharmacist (R.Ph), Mr. Newkirk was the chief billing and compliance consultant for compounding retail pharmacies on behalf of his company, Freedom Pharmaceuticals. Mr. Newkirk taught a bi-monthly class on how to correctly model one's business to best perform in compliance with ever-changing PBM manuals, contracts and the resulting PBM audits. Since 2018, Mr. Newkirk has worked in pharmacy compliance consulting primarily with independent pharmacies in connection with audits by PBMs, pharmacy operations, policy and procedures, billing practices, and contractual reviews. Mr. Newkirk bases his opinion on his review of the PBM manuals, Provider Agreements, Membership Enrollment forms and other Rule 16 discovery, all of which has been made available to him.

Newkirk Discl. In a case such as this where the expert opinion is based on the expert's knowledge and experience rather than some scientific methodology, Mr. Newkirk's decades of experience in the pharmaceutical industry and over ten years as an auditor reviewing the practices and

submissions of pharmacies such as Central Rexall, in addition to his years working as a mail order pharmacist and manager, plainly provide sufficient bases and reasons to support his noticed opinions.

4. David S. Joseph, R.Ph, FIACP

David Joseph has been offered by the defense as an expert to opine on pharmacy practices, the use of pre-printed prescription pads, the pharmaceutical industry's universal practice of initiating "test claims," and the normalcy of physicians prescribing compounded medications. Joseph Discl. The Government reiterates its misleadingly narrow view of evidence relevant to the charges it has brought in arguing that Mr. Joseph's disclosed expert opinions on "the duties of pharmacists (including the Pharmacist in Charge) and physicians," the use of "preprinted prescription pads," and "test claims" or "test adjudications" are "not relevant to the defendants' guilt or the issues in this case." Gov. Br. at 16. Indeed, the Government audaciously characterizes Mr. Joseph's opinion that "the pharmaceutical industry's universal practice of initiating 'test claims' or 'test adjudications,' [] incur no financial loss to any person or entity when test adjudications are 'cancelled,' or, in other words, not submitted as actual claims," Joseph Discl., as suggesting that "the entire pharmaceutical industry universally engaged in identity theft and makes false claims." Gov. Br. at 16. But aside from the inflammatory and unduly conclusive nature of the Government's statement, it again highlights why expert testimony as to the definition, function, and attendant practices described as "means" of the fraud alleged here, such as "test adjudications," is necessary: the Government very clearly attempts to portray what defendants are alleged to have done as sinister or unusual when an expert in the field would know that this is not true. The Government will, of course, have the right to challenge those conclusions, but the jury should be permitted to hear them and decide whether Central Rexall's actions—whether test adjudications or pre-printed prescription pads—were consistent with industry practice, an important fact that

requires expertise, particularly given the Government's effort to characterize them as it does. For the reasons previously set forth with regard to other experts, *see infra* Sec.II.A and Sec.II.B.1-3, these opinions should be allowed here.

The Government moreover makes no mention in its moving brief of Mr. Joseph's disclosed opinions with regard to compounded medications, opinions about which he was permitted to testify in another compounding case in this District. *See* Joseph Discl.:

> [I]t is normal and proper for physicians to prescribe compounded medications in accordance with their professional judgment, whether or not the physician first tried to address a particular patients' medical needs with single-ingredient or non-compounded medication, and that compounded medications can be used as alternatives to other medications, including opioids, and are at times preferable to traditional pharmaceutical medications in the estimation of some physicians for certain patients.

At the very least then, he should be permitted to opine on these subjects, which, as discussed below, are implicated by the Government's insinuations in its Indictment that compounded pharmaceuticals are not safe, efficacious or of the same high quality as other products, and thus, cannot be medically necessary (from which the Government draws the conclusion that providing them was fraudulent). *See supra* Sec. II.B.2-3.

Finally, the Government again posits that "Joseph has completely failed to explain how or what he did to familiarize himself with the facts of this case or what method he used to reach his opinions," challenging the bases and reasons for his opinions. Gov. Br. at 17. But as set forth above with respect to the other defense experts, and as is elaborated more fully *supra*, Sec.I.B, experience, in conjunction with specialized knowledge, can provide a sufficient basis for qualifying a witness an "expert," whose applied methodology, in turn, is highly case and specialty specific. *See Xue*, 597 F. Supp. 3d 759, 766; *Kumho Tire Co.*, 526 U.S. at 156. To the extent the Government challenges the "bases and reasons" of Mr. Joseph's disclosed expert opinions as

inadequately specific under Rule 16, those, once again, have been provided in Mr. Joseph's disclosure, along with his curriculum vitae:

> These opinions are based on Mr. Joseph's 51 years' experience as a pharmacist. More specifically, between 2014 and 2016, Mr. Joseph ran a compounding pharmacy that provided topical medications. This pharmacy was also a mail-order pharmacy and provided its medications to all fifty states. As a pharmacist, he is aware of the industry standards and practices and has considerable experience in both federal and state regulatory compliance. . . .

Joseph Discl. As Mr. Joseph's expert opinions are based on his knowledge and experience, including over fifty years as a pharmacist, including at a mail-order compounding pharmacy during the precise time period at issue in this case, he is uniquely qualified to opine on the issues implicated here and this background provides far more than adequate bases and reasons to support his noticed opinions.

5. Carol Weinman, Esq.

Finally, the defense has offered Carol Weinman to testify, if necessary, that "elements of Mr. Johnston's behavior include difficulties developing, maintaining, and understanding relationships, and his ability to mask his autistic traits." Weinman Discl. The Government's moving brief hints that Weinman's proposed testimony is irrelevant because Mr. Johnston was diagnosed with autism two years after he was indicted and six years after the conduct at in this case. Gov. Br. at 17. Additionally, the Government argues that the defense has not provided the Government with "any idea of what she will talk about." *Id*. at 18. In particular, the Government speculates that Ms. Weinman will provide impermissible opinion evidence about Mr. Johnston's willfulness. *Id*. at 19. But this is simply not true. Ms. Weinman's disclosure clearly states that while, she will be able to provide testimony regarding conduct that individuals with ASD may exhibit, if that becomes relevant to the case, she "will not, however, opine as to whether Mr. Johnston in fact held any specific mental state or belief at any specific time." Weinman Discl. *See*

United States v. Moore, No. 3:20-cr-00029-SLG, 2022 U.S. Dist. LEXIS 49166, at *10 (D. Alaska Mar. 21, 2022) (district court denied the government's motion without prejudice to renew it objections later because "the defense cannot predict the exact nature of its expert's testimony until [after] the government's case.").

Not surprisingly, courts have found expert testimony regarding autism "relevant and reliable." *See United States v. Huber*, No. 8:23-cr-391-CEH-SPF, 2024 U.S. Dist. LEXIS 146241, at *4 (M.D. Fla. Aug. 16, 2024) (the district court denied the Government's motion, allowing an expert to testify regarding defendant's autism playing a role in his actions relevant to the associated charges). Thus, Ms. Weinman's testimony will help the jury understand and contextualize Mr. Johnston's behavior, to the extent the Government argues to the jury, or produces proof, that characteristics consistent with Mr. Johnston's autism diagnosis may establish his criminal conduct. One example, which counsel for Mr. Johnston disclosed to the Government in meeting and conferring prior to this motion practice, was that Ms. Weinman, who is clearly qualified, and based upon her experience and expertise has a basis to opine,[4] could explain that among Mr. Johnston's "autistic traits" is a garrulousness that may explain the length of certain conversations, should the length of those conversations be an issue at trial. Weinman Discl. ("It may also include general isolating behaviors, hyper-focus on a specific individual issue or person and excessive garrulousness."). If, on the other hand, no such testimony or evidence is admitted at trial, and no such argument advanced, Mr. Johnston does not intend to offer Ms. Weinman's expert opinions.

[4]"These opinions are based on Ms. Weinman's experience as an autism legal consultant, autism expert, autism behaviorist, parent of an autistic son, and as an autism lawyer… she represented criminal defendants with ASD and students with special needs in regards to special education, bullying, suspension, and expulsion. In 2010, she founded Autism Advisors & Advocates, LLC, which educates, trains, and consults parents and professionals…She has conducted numerous CLEs and presented at the U.S. Autism Annual World Conference 2020-2024[.]" Weinman Discl.

CONCLUSION

For these reasons, the expert disclosures for each of Mr. Johnston's proffered expert witnesses sufficiently comply with Rule 16 and their disclosed testimony clearly addresses technical and industry-specific issues that are at the heart of this case and will assist the jury to understand the evidence and testimony presented. The Government's Motion to Exclude Defense Experts should be denied.

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Respectfully submitted,

s/ Lawrence S. Lustberg
Lawrence S. Lustberg
Anne M. Collart
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07030
(973)596-4500
Attorneys for Defendant
Christopher Kyle Johnston